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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,094	01/03/2001	Mark S. Humayun	55534 (71699)	4130

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EXAMINER

SERKE, CATHERINE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/24/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/754,094	HUMAYUN ET AL.
Examiner	Art Unit	
Catherine Serke	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication;
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 01 November 2002.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-35 and 39-57 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-35 and 39-57 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 03 January 2001 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.5. 6)  Other: \_\_\_\_ .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that now the amended claims incorporate the use of the apparatus of any of claims 1 to 3. Upon review of the amendments the restriction is no longer applicable.

However, the election of species requirement is still valid. Reviewing the groupings of the species in the election of species requirement, it is noted that grouping "a" has an error and should have read:

- a. Figs 1 and 5-11.

This error may account for applicant's traversal of the election of species requirement. It is the examiners belief that the above correction should eliminate the traversal. Also, it is inferred that even with the correction, applicant would still elect species "a". Therefore, the claims reading on species "a" are addressed below.

Furthermore, applicant elected Species A but failed to list all claims readable thereon which was a requirement of the restriction (see page 3 paragraph 2 of the previous office action). The paragraph reads "Applicant is advised that a reply to this requirement must includes an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added**". [Emphasis added]. In order to expedite prosecution, the examiner has reviewed the claims in light of the species and has determined that claims 1-36 and 39-57 are readable thereon.

The requirement is still deemed proper and is therefore made FINAL.

***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: wire 30. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Specification***

The disclosure is objected to because of the following informalities: page 15 of the specification references the larger cannula as #12 whereas the drawings use reference #14.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-33 and 39-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5,8,9,12,24,25 and 39 recite the limitation "the flexible cannula" or "the cannula". There is insufficient antecedent basis for this limitation in claim 1 which fails to positively set forth a flexible cannula or any cannula.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
  - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
  - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-4, 12-16, 19 and 25-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Le et al (US Pat# 6,355,027).

Le discloses a flexible microcatheter system having a flexible cannula (16) with a proximal end and a distal end. The system also has a second cannula (14) having a larger diameter than the flexible cannula and is less flexible (1:46-49). The second cannula has a proximal end and a distal end and a portion of the flexible cannula is housed within the distal end of the second cannula (see figures 1-3). The second cannula forms a fluid tight seal and mounted about the flexible cannula (see figure 3; the mounting of cannula 14 and 16 within proximal connector 12 must be fluid tight between all three components in order to prevent leaking). The proximal end of the second cannula is sized for attachment (connector 12) to the tip of a syringe.

Regarding the function language in claims 1-4, 16, 25-33 that generally provide for the functioning of the microcatheter or cannula as a hands free injection system. The examiner reminds applicant that function language in device claims is given little patentable weight. As long as the prior art device meets the structural limitations of the claims and is capable of performing the claimed function then the prior art reads on the claims.

In the claims above, the instant invention is a device that injects into the retinal vein of the eye for periods of time from at least 5 min to 2 hours using no support systems to hold the device in position and provides an infusion flow rate of 0.2 cc/min through the proximal end of the second cannula. The prior art is capable of performing this function due to the fact that it is a microcatheter for use in small and tortuous vascular paths and is made from flexible materials.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Weiss (US Pat# 6,402,734). Le meets the claim limitations as stated above but fails to include the distal end being sharp and rigid with a bevel at about 30°.

Weiss discloses an apparatus and method for cannulating retinal blood vessels. The device includes a microcannula with a beveled end (see figure 1).

At the time of the invention, it would have been obvious to incorporate a beveled end into the invention of Le. Both devices are for fluidic transfer/infusion at a micro level into small vasculature; therefore, a combination is proper. The motivation for the incorporation would have been to eliminate the need for an introducer catheter to penetrate the vessel before the insertion of the cannula into the vessel thereby making the device easier to use.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Weiss (US Pat# 6,402,734). Le meets the claim limitations as stated above but fails to include the flexible cannula being illuminated for enhanced visibility.

Weiss discloses an apparatus and method for cannulating retinal blood vessels. The device includes a fiber optic positioned parallel with the cannula for enhanced visibility during use (see figure 3).

At the time of the invention, it would have been obvious to incorporate the fiber optic into the invention of Le. Both devices are for fluidic transfer/infusion at a micro level into small vasculature; therefore, a combination is proper. The motivation for the incorporation would have been to enhance the surgeon's visibility of the vascular during use thereby increasing the patient's safety during the procedure.

Claims 8-11 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le. Le meets the claim limitations as described above but fails to include the cannula being made from polyimide and having the flexible cannula and second cannula dimensions of claims 9-11 and 17-18 .

At the time of the invention it would have been obvious to make the cannula from a material such as polyimide since the catheter is disclosed as having flexible properties and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The motivation for using a medical grade plastic such as polyimide would have been in order to reduce the incidence of allergic reaction of the skin to contact with non-medical grade plastic materials.

Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le in view of Castora (US Pat# 5947296). Le meets the claim limitations as described above but fails to include a kit including one or more of the catheters packed in sterile conditions.

Castora discloses a catheter kit with multiple catheters packaged in one kit. See figures.

At the time of the invention, it would have been obvious to package the catheter of Le as per the organization of Castora since packaging catheters is well known and considered inherent in the art if the catheter is planned for human use.

#### *Allowable Subject Matter*

Claims 20-23 and 39-57 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### *Conclusion*

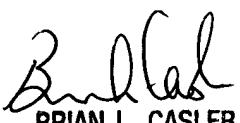
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *BS*  
January 16, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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